

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 5 1995

Mr. Don Emlay  
Vice President, Regulatory affairs  
Calgene, Inc.  
1920 Fifth Street  
Davis, CA 95616

Dear Mr. Emlay:

This is in regard to your genetically modified bromoxynil tolerant cotton about which you initiated consultations with the agency in August 1992. The new cotton variety has been rendered tolerant to bromoxynil by expression of a nitrilase from *Klebsiella ozaenae*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new cotton variety on June 14, 1994. On October 21, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by Calgene to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded, in essence, that the new cotton variety is not significantly altered in composition, safety, or any other relevant parameter from cotton varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0004 and that will be maintained in the Office of Premarket Approval.

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Based on the description of the data and information presented during the consultations, the new cotton variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is Calgene's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.  
Acting Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247  
HFS-013 HFV-221 BNF 0004